COMMISSION DECISION

of 30 March 2007

concerning a Community financial contribution towards a baseline survey on the prevalence of *Salmonella* in slaughter pigs to be carried out in Bulgaria and in Romania

(notified under document number C(2007) 1394)

(Only the Bulgarian and Romanian texts are authentic)

(2007/219/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], and in particular Article 20 thereof,

Whereas:

(1) Decision 90/424/EEC provides for Community financial contributions towards specific veterinary measures. It also provides for the Community to undertake or assist the Member States in undertaking the technical and scientific measures necessary for the development of veterinary legislation and for the development of veterinary education or training.

(2) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents [2], provides that a Community target is to be established for the reduction of the prevalence of *Salmonella* in populations of herds of slaughter pigs by the end of 2007.

(3) During its meeting of 16 March 2006, the Scientific Panel on Biological Hazards of the European Food Safety Authority (EFSA) adopted an Opinion on the request from the Commission related to 'Risk assessment and mitigation options of *Salmonella* in pig production'. That opinion proposes technical specifications for a baseline study on the prevalence of *Salmonella* in fattening pigs in the Community.

(4) In order to set the Community target, comparable data on the prevalence of *Salmonella* in populations of slaughter pigs in Bulgaria and in Romania needs to be available. Such information is presently not available and a special survey should therefore be carried out to monitor the prevalence of *Salmonella* in slaughter pigs over a suitable period in those Member States.

(5) A baseline study on *Salmonella* in fattening pigs is to be carried out by the other Member States between October 2006 and September 2007 in accordance with Commission Decision 2006/668/EC of 29 September 2006 concerning a financial contribution from the Community towards a baseline survey on the prevalence of *Salmonella* in slaughter pigs to be carried out in the Member States [3]. The same procedures should be used in the baseline studies in Bulgaria and in Romania. However, the period of the survey should be shortened in order to enable the analysis of the data of all Member States at the same time.

(6) The EFSA opinion recommends slaughterhouse sampling by taking ileocaecal lymph nodes to reflect the *Salmonella* status of pigs sent to slaughter. Such sampling should therefore be used as a tool to monitor the prevalence of *Salmonella* in slaughter pigs.

(7) The survey is to provide the technical information necessary for the development of Community veterinary legislation. Given the importance of collecting comparable data on the prevalence of *Salmonella* in fattening pigs in Bulgaria and in Romania, those Member States should be granted a Community financial contribution for implementing the specific requirements of the survey. It is therefore appropriate to reimburse 100 % of the costs incurred in the laboratory testing, subject to a ceiling. All other costs, such as those relating to sampling, travel and administration should not be eligible for any Community financial contribution.

[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

[2] OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006.

[3] OJ L 275, 6.10.2006, p. 51.

(8) The financial contribution from the Community should be granted provided that the survey is carried out in accordance with Community law and subject to compliance with certain other specified conditions. In particular, the financial contribution should be granted in so far as the actions provided for are effectively carried out and provided that the authorities furnish all the necessary information within the time limits provided for.

(9) It is necessary to clarify the rate to be used for the conversion of payment applications submitted in national currencies as defined in Article 1(d) of Council Regulation (EC) No 2799/98 of 15 December 1998 establishing agrimonetary arrangements for the euro [1].

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. A survey shall be carried out to assess the prevalence of *Salmonella* spp. in Bulgaria and in Romania in slaughter pigs sampled in slaughter houses in those Member States (the survey).

2. The survey shall cover a period from 1 April 2007 to 30 September 2007.

3. For the purposes of this Decision, 'the competent authority' shall be the authority or authorities of a Member State, as designated under Article 3(1) of Regulation (EC) No 2160/2003.

Article 2

Technical specifications

The sampling and analysis for the purposes of the survey shall be performed by the competent authority or under its supervision in accordance with the technical specifications set out in Annex I.

Article 3

Collection of data, assessment and reporting

1. The competent authority shall collect and assess the results achieved pursuant to Article 2 of this Decision and shall report all necessary aggregated data and its assessment thereof to the Commission.

The Commission shall forward those results together with the national aggregated data and assessments done by the Member States to the European Food Safety authority, which shall examine them.

2. The national aggregated data and results referred to in paragraph 1 shall be made available publicly in a form that ensures confidentiality.

Article 4

Community financial contribution

1. A Community financial contribution shall be granted to Bulgaria and Romania for the costs incurred by them for laboratory testing, i.e. for the bacteriological detection of *Salmonella* spp., and the serotyping of the relevant isolates and serology.

2. The maximum Community financial contribution shall be:

(a) EUR 20 per test for bacteriological detection of *Salmonella* spp.;

(b) EUR 30 per test for serotyping of the relevant isolates.

However, the Community financial contribution shall not exceed the amounts set out in Annex II.

Article 5

Conditions for granting a Community financial contribution

1. The financial contribution provided for in Article 4 shall be granted to Bulgaria and to Romania provided that the survey is implemented in accordance with the relevant provisions of Community law, including the rules on competition and on the award of public contracts, and subject to compliance with the following conditions:

(a) the laws, regulations and administrative provisions required to implement the survey shall come into force by 1 April 2007 at the latest;

(b) a progress report covering the first three months of the survey shall be forwarded by 31 July 2007; the progress report shall contain all information requested in Annex I;

[1] OJ L 349, 24.12.1998, p. 1.

(c) a final report shall be forwarded by 31 October 2007 at the latest, on the technical execution of the survey, together with supporting evidence for the costs incurred and the results attained during the period 1 April 2007 to 30 September 2007; the supporting documents concerning the costs incurred shall comprise at least the information set out in Annex III;

(d) the survey shall be implemented effectively.

2. An advance payment of 50 % of the total amount referred to in Annex II may be paid at the request of Bulgaria or of Romania.

3. Failure to comply with the time limits provided for in paragraph 1(c) shall entail a progressive reduction of the Community financial contribution to be paid, amounting to 25 % of the total amount by 15 November 2007, 50 % by 1 December 2007 and 100 % by 15 December 2007.

Article 6

Conversion rate for expenditure

For reasons of administrative efficiency all expenditure presented for a financial contribution by the Community should be expressed in euro. In accordance with Commission Regulation (EC) No 1913/2006 of 20 December 2006 laying down detailed rules for the application of the agrimonetary system for the euro in agriculture and amending certain regulations [1], the conversion rate for expenditure in a currency other than the euro should be the rate most recently set by the European Central Bank prior to the first day of the month in which the application is submitted by the Member State concerned.

Article 7

Application

This Decision shall apply from 1 April 2007.

Article 8

Addressees

This Decision is addressed to the Republic of Bulgaria and to Romania.

Done at Brussels, 30 March 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 365, 21.12.2006, p. 52.

ANNEX I

Technical specifications in accordance with Article 2

1. **Sampling frame**

A minimum number of pigs, kept during at least the preceding three months in the Member State, shall be sampled, at random, as follows:

Bulgaria: 192

Romania: 300

Bulgaria and Romania shall take a 10 % extra number of samples, to be analyzed in case some samples excluded from the study for various reasons.

Sampling shall be stratified by slaughterhouses that participate and proportional to slaughterhouse capacity. Each of those Member States shall rank all slaughterhouses according to their fattening pig throughput in the previous year. Thus, they shall each identify those plants that accounted for at least 80 % of all slaughtered fattening pigs.

The total number of pigs and carcasses to be sampled in each of the slaughterhouses included in the study shall be estimated by multiplying the sample size (for example, 2 400) by the proportion of fattening pigs processed in the previous year. For example, if one slaughterhouse accounted for 25 % of fattening pigs slaughtered in the selected slaughterhouses (those representing at least 80 % of all fattening pigs slaughtered in the Member State), then (2 400 × 0,25) 600 pigs shall be sampled. These shall be evenly divided so that 50 pigs sampled in every month, for 12 months. A further example is shown in Table 1.

However, if a slaughterhouse is no longer in production, if a new facility has been opened or there is predicted to be a significant change in plant throughput during the survey, then the estimated throughput shall be adjusted accordingly.

Table 1

Weighing of slaughterhouses for the purpose of allocating the number of fattening pigs to be sampled from each slaughterhouse; calculation of sampled animals per slaughterhouse

Slaughterhouse ID	Number of fattening pigs processed previous year	Percent of total slaughter included in the study	Number of samples per slaughterhouse	Samples per month (/12)
AXD	88 000	17,6	0,176 × 2 400 = 422,4	422,4 : 12 = 36
SVH	25 000	5,0		
TPB	75 000	15,0		
MLG	100 000	20,0		
GHT	212 000	42,4		
Total	500 000 (1)	100,0		

(1) This number must represent at least 80 % of slaughtered fattening pigs in a Member State.

For each slaughterhouse each month, a number between 1 and 31 shall be selected at random. If the randomly selected number is a slaughtering day, for that month, then that day is selected for sampling. If not, then a new number shall be selected randomly. This process shall be performed once a month and repeated as many times as there are samples to be collected at the slaughterhouse. For example, in the slaughterhouse AXD the process shall be repeated at least 36 times to select at least 36 working days randomly. Accordingly, there may be more than one carcass to be sampled on the same day.

As the number of animals slaughtered on a specific day may vary enormously, the random selection of the individual animal shall take place at the slaughterhouse at the date randomly selected for sampling. The given day, the total number of animals must be known, and the personnel of the slaughterhouse shall then randomly select a carcass or carcasses using the randomization sheet which has been provided to them and which has been generated using a maximum that exceeds the highest possible number of fattening pigs slaughtered on any given day in any slaughterhouse in the Member State.

A randomization table may then look as shown in Table 2.

Table 2

Randomization table.

Slaughterhouse	Day of the month	Identity of carcass ([1])
AXD	19	5
	4	2
	12	124
	12	2
	8	59

([1]) The 5th carcass to be processed on the 19th day of that month should be sampled for the survey.

The following animals shall be excluded from the baseline study:

— animals with a live weight of less than 50 kg or more than 170 kg,

— animals that have undergone emergency slaughter,

— any carcass that is totally condemned.

2. **Samples**

2.1. *Sampling in general*

— The aggregate of ileocaecal lymph nodes or at least five individual ileocaecal lymph nodes of all selected pigs shall be collected. If possible, at least 25 grams of lymph nodes without fat or connective tissues shall be collected.

— Records shall be kept at the slaughterhouse on the date and time of sampling of each sample and the date and time and name of the courier that takes delivery of the samples.

2.2. *Details on sampling of ileocaecal lymph nodes*

The mesenterium between the caecum and the part of the ileum that is closest to the caecum shall be torn and the ileocaecal lymph nodes are presented at the surface of the torn-open area. Without a knife, but with gloved fingers, the lymph nodes shall be bluntly 'harvested' from such opened mesenterium if individual lymph nodes are collected. The lymph nodes or the aggregate shall be placed in a plastic bag which is marked with date, time, slaughterhouse identification and sample identification code.

3. **Transport**

Samples shall be sent within 36 hours by express mail or courier and shall reach the laboratory no later than 72 hours following sampling. Samples arriving more than 72 hours following sampling shall be discarded unless the analysis is initiated within 96 hours following sampling and the cold chain has not been interrupted.

4. **Analysis and serotyping of samples**

Analysis and serotyping of samples shall take place at the national reference laboratory (NRL). Where the NRL does not have the capacity to perform all analyses or if it is not the laboratory that performs detection routinely, the competent authorities may decide to designate a limited number of other laboratories involved in official controls of *Salmonella* to perform the analyses.

Those laboratories must have proven experience of using the required detection method and have a quality assurance system complying with ISO standard 17025 and be subject to the supervision of the NRL.

At the laboratory, samples shall be kept refrigerated until bacteriological examination, which shall be carried out within 24 hours following receipt of the samples so that analysis is initiated no later than 96 hours following the time of collection of the samples.

4.1. *Sample preparation*

Lymph nodes shall be surface de-contaminated before analysis by dipping into absolute alcohol and drying by air.

All lymph nodes shall be pooled and closed in a plastic bag and banged with a hammer or by similar means on the plastic bag smashing the lymph nodes.

The homogenized lymph nodes shall be weighed and placed in a sterile container with pre-warmed buffered peptone water (BPW) in dilution 1:10. Containers shall be incubated for a total of (18 ± 2) hours at (37 ± 1) °C.

4.2. *Detection method*

The method recommended by the Community Reference Laboratory (CRL) for *Salmonella* in Bilthoven, the Netherlands, shall be used.

That method is described in the current version of draft Annex D of ISO 6579:2002: 'Detection of *Salmonella* spp. in animal faeces and in samples of the primary production stage'. In this method, the modified semi-solid Rappaport-Vassiladis (MSRV) medium shall be used as the single selective enrichment medium.

4.3. *Serotyping*

All strains isolated and confirmed as *Salmonella* spp. shall be serotyped according to the Kaufmann-White scheme.

For quality assurance, 16 typable strains and 16 non-typable isolates shall be sent to the CRL. If less strains have been isolated, all shall be sent.

4.4. *Phage typing*

In the case where isolates of *Salmonella* serovar *Typhimurium* and *Salmonella* serovar *Enteritidis* are phage typed (optional), the methods described by WHO reference centre for phage typing of *Salmonella* of the Health Protection Agency (HPA), Colindale, UK, shall be used.

4.5. *Testing of anti-microbial susceptibility*

In the case of testing for anti-microbial susceptibility (optional), a validated and controlled method for testing shall be used, such as those recommended by the National Committee for Clinical Laboratory Standards (NCCLS, since 1st of January 2005: 'Clinical and Laboratory Standards Institute' — CLSI).

Both agar diffusion and broth dilution methods shall be acceptable. Results shall be reported both as quantitative data (MIC for dilution methods and inhibition zone diameter for diffusion methods) and as qualitative data (proportion resistant isolates).

Qualitative data shall be based on interpretation according to epidemiological cut-off values presented by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) at: http://www.eucast.org

The isolates shall be tested for the susceptibility to the antimicrobial substances listed below:

— Ampicillin or Amoxicillin

— Tetracycline

— Chloramphenicol

— Florfenicol

— Nalidixic acid

— Ciprofloxacin (preferably) or Enrofloxacin

— Sulphonamide (preferably Sulfametoxazole)

— Sulphonamide/Trimethoprim or Trimethoprim

— Gentamicin

— Streptomycin

— Kanamycin (preferably) or Neomycin

— 3rd generation cephalosporin, (preferably cefotaxime)

— Colistin (optional)

Before initiation of the study the two Member States shall organise training for the involved parties.

5. **Records and sample storage**

Records of bacteriology shall be kept on all samples processed in a format in accordance with or comparable to the example given in Table 3.

All strains isolated shall be stored at the NRLs of the two Member States as long as it ensures integrity of the strains for a minimum of five years.

All samples of meat juice for serology shall be stored frozen for two years.

Table 3

Example of records to be taken on all processed samples

Sample				Receipt					Analysis			
Sample ID + type	Slaughterhouse ID	Name	Date	Time	Name	Date	Time	Pos or Neg	Serovar	Phagetype	Antibiogram	Storage ID
1 S	EU012	PW	3-10-06	12:00	AB	3-10	14:00	Neg				
2 L	EU023	PW	4-10	12:30	AB	4-10	14:00	Pos	Typh	DT104	ASTSu	(IDnr)
3 L	EU083	PW	8-10	16:30	AB	9-10	9:00	Pos	Agona	n.a.	ASTE	(IDnr)
Etc												

6. **Reporting from Bulgaria and Romania**

The competent authority responsible for the preparation of the yearly national report on the monitoring of *Salmonella* in animals pursuant to Article 9 of Directive 2003/99/EC shall collect and evaluate the results and report to the Commission.

Those reports shall include at least the following information:

6.1. *Overall description on the implementation of the survey programme*

— description of the population under study stratified according to slaughterhouses capacity,

— description of randomization procedure, including notification system,

— sample size calculated,

— details of authorities and laboratories involved in sampling/testing/typing,

— overall results of the study (samples analyzed by bacteriology, number of positive, serovar, phage type and antibiotic resistance testing).

6.2. *Complete data on each animal sampled and corresponding tests results*

The Member States shall submit the results of the survey in the form of raw data using a data dictionary and data collection forms provided by the Commission.

That dictionary and forms shall be established by the Commission and include at least the following:

— reference of the slaughterhouse,

— capacity of the slaughterhouse,

— date and time of sampling,

— reference of the samples (the number),

— type of samples taken: lymph nodes,

— date of dispatch to the laboratory.

The following information shall be collected in the Member States for each sample sent to the laboratory:

— ID of the laboratory (in case several laboratories are involved),

— means of transport of samples,

— date of reception by the laboratory,

— when testing lymph nodes, weight of the specimen,

— results for the individual samples tested: 'negative' or in case positive for *Salmonella* spp., also the results of serotyping '*Salmonella* serovar' or 'untypable',

— results for strains subject to antimicrobial susceptibility testing and/or phagetyping results.

ANNEX II

Maximum Community financial contribution to Bulgaria and Romania

(EUR)

Member State	Amount
Bulgaria	4 992
Romania	7 800

ANNEX III

Certified financial report on the implementation of a baseline survey on the prevalence of *Salmonella* spp. in herds of slaughter pigs

Reporting period: 1 April 2007 to 30 September 2007

Statement on costs incurred on the survey and eligible for Community financial contribution

Reference number of Commission Decision providing Community financial contribution: .....

.....

Costs incurred related to functions at/by	Number of tests	Total costs of testing incurred during reporting period (national currency)
Bacteriology for *Salmonella* spp.		
Serotyping *Salmonella* isolates		

Declaration by the beneficiary

We certify that

— the costs set out in the statement on costs are genuine and have been incurred in carrying out the tasks laid down in Commission Decision 2007/219/EC and were essential for the proper performance of those tasks;

— all supporting documents for those costs are available for audit purposes.

Date: .....

Person financially responsible: .....

Signature: .....